

REMARKS

Claims 18-60 are pending in this application. With this response, claims 18, 21, 26, 42, 47, and 52 have been amended, and claim 25 has been canceled without prejudice. No new matter is added by amendment. Support for the amendments can be found in paragraphs [0042], [0051], [0053] and [0057] of the specification of the published application, US 2004/0193137 Al. Reconsideration of the claims as amended, in light of the remarks that follow, is respectfully requested.

Rejections over Humes (U.S. 5,911,704)

Claims 18-31, 35-56, 59, and 60 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Humes. Applicant disagrees with those rejections for the reasons stated in the Amendment filed June 16, 2008. Nevertheless, to advance prosecution of this application, Application has again amended claims 18, 26, 42, 47, and 52 to patentably distinguish over Humes, both alone and in combination with the other prior art of record.

In particular, claim 18 has been amended to recite that “at least one of the expandable anchor and eluting material including an anti-clotting agent.” As disclosed in the above-cited paragraphs of the specification, the purpose of this anti-clotting agent is to prevent clot formation within or around the anchor and eluting material. Humes does not disclose or suggest a method that includes releasing an anti-clotting material into the blood flowing through the eluting material or anchor to prevent clot formation, as recited in claim 18 as amended.

Incredibly, Humes discloses that it would be *advantageous to create an autologous blood clot* and use that clot as “a biocompatible gel” to encase the hollow fibers containing cells disclosed in that application. The mass of hollow fibers and clot would thus “produce a plug that may be captured by the blood permeable element (see, for example, plug 50, in FIG. 6C).” Hume’s provides no understanding or explanation as to why such an autologous blood clot would *not* activate the platelets in blood passing around the capsule, and thus result in potentially lethal and systemic thrombus formation leading to ischemia and stroke. To say the least, Humes specifically *teaches away* from Applicant’s inventive apparatus and methods *by encouraging the use of blood clots* formed from autologous blood, whereas

Applicant specifically seeks ***to prevent blood clots*** that could have potentially disastrous ramifications for the patient. Not only does Humes not teach or suggest the use of anti-clotting agents, the use of such agents with Humes apparatus would likely dissolve the autologous clot used to bind the hollow cell-filled fibers together, presumably leading to failure of the device and potentially lethal migration of the hollow cell-filled fibers. Claims 26, 42, 47, and 52 have been likewise amended to incorporate this stark distinction between Applicant's inventive methods and apparatus and that disclosed in Humes.

Applicant respectfully submits that there is no conceivable interpretation of Humes, either alone or in combination with the other prior art of record, that could support an unpatentability rejection of Applicant's amended claims.

In addition, claim 18 has been further amended to recite that the anchor is reversibly expandable, and to recite further steps of collapsing the anchor to the delivery configuration and retrieving the anchor transluminally with a catheter. Humes discloses no such steps, instead disclosing only “[i]t is contemplated, however, that exhausted cell capsules, i.e., wherein a substantial fraction of cells within the capsule are no longer viable or no longer secrete the 25 pre-selected molecule, may be retrieved from the recipient and replaced with new capsules containing fresh cells that produce and secrete the pre-selected molecule.” Column 8, lines 22-27. Notably, Humes provides no explanation how this is done. One of ordinary skill in the art would recognize that after having been disposed within the vessel for “a prolonged period of time, preferably in range of months to years,” the neointimal growth will have permanently affixed the anchor portion of Humes device to the vessel, thus making transluminal retrieval impossible. That is why in each of the Examples described in Humes the animal was sacrificed to surgically retrieve the device for examination. See, e.g., Column 21, lines 2-5; lines 45-48; Column 24, lines 37-40 and Column 25, lines 17-20. Applicant respectfully submits that the amendments to claim 18 further patentably distinguish over Humes.

Rejections over Humes in view of Leong (WO 95/26168)

Claims 32-34, 57, and 58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Humes in view of Leong.

Leong does not remedy the defect in Humes regarding the advantage of employing an anti-clotting agent with Applicant's inventive apparatus. As noted above, not only is such use not contemplated by Humes, but the use of an anti-clotting agent with that device would have

potentially disastrous effect. A similar observation applies to Leong, which teaches the benefit of loading a platelet-derived growth factor (PDGF) into the foam scaffolding described in that reference, since the anti-clotting agent and PDGF may be working at cross-purposes, the former intended to promote cell adhesion to the foam scaffolding and the latter intended specifically to prevent such growth. Applicant respectfully submits that because Leong cannot supplement the missing element in Humes, which is in any event antithetical to the teaching of that reference, Applicant's amended claims patentably distinguish over the prior art of record, alone and in combination.

Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

No fee is believed to be due with the filing of this response. However, please charge any required fee, or any overpayment, to Jones Day Deposit Account No. 50-3013.

If the Examiner believes it would be useful to advance prosecution, the Examiner is invited to telephone the undersigned at (858) 314-1200.

Respectfully submitted,

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